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| EXAMINER | | | | |
| PAULS, JOHN A | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,873

Applicant(s)

ALSAFADI ET AL.

Examiner

JOHN A. PAULS

Art Unit

4114

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 07 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/ISD)
Paper No(s)/Mail Date 7 June 2005
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 7 June, 2005
2. Claims 1 - 18 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statement filed on 7 June, 2005 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show descriptions of the invention's component parts as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: reference numbers for "plug-in factory (48); execution engine (50) and application (46) are incorrect as shown on page 5 of the disclosure.
- Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites "*substantially no interaction...*". The term "*substantially*" is vague and indefinite.
8. **Examiner's Note:** The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
- A person shall be entitled to a patent unless –
- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 17 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Killcommons et al. (US 6,424,996 B1).

CLAIM 17

Killcommons as shown discloses the following limitations:

- *a computer-readable storage medium (34), responsive to a diagnostic medical modality (21); (see at least Kilcommons column 4 line 54 – 58);*
- *for storing a metric (12) automatically downloadable to the diagnostic medical modality (21) from the World Wide Web (18); (see at least Kilcommons column 7 line 23 – 43; column 7 line 52 – 55; column 7 line 44 – 46; column 13 line 7 – 16 and column 16 line 29 – 54);*
- *the metric (12) comprising:*
 - *predetermined criteria for performing a clinical medical calculation in connection with the medical investigation; (see at least Kilcommons column 6 line 53 – 58 and column 16 line 29 - 54);*
- *a processor (36) responsive to the computer-readable storage medium (34) and to a software program (38); (see at least Kilcommons column 4 line 54 – 67);*
- *the software program (38), when loaded into the processor (36) operative to cause the diagnostic medical modality (21) to conduct the clinical medical calculation based on the metric (12); (see at least Kilcommons column 4 line 54 – 67 and column 16 line 29 - 67).*

CLAIM 18

Killcommons as shown discloses the following limitations:

- *providing, in a computer-readable storage medium (13), a plurality of metrics (12) associated with a plurality of diagnostic medical modalities (17, 19, 21); (see at least Kilcommons column 4 line 54 – 58; column 7 line 23 – 43; column 7 line 52 – 55 and column 16 line 29 – 54);*
- *the metrics (12) comprising:*
 - *predetermined criteria for performing clinical medical calculations using diagnostic medical modalities (17, 19, 21); (see at least Kilcommons column 6 line 53 – 58 and column 16 line 29 - 54);*

- *prior to at least one of the plurality of diagnostic medical modalities (17, 19, 21) performing a clinical medical calculation; causing at least one of the plurality of metrics (12) to be automatically downloaded to the at least one diagnostic medical modality (21) via the World Wide Web (18); (see at least Kilcommons column 4 line 27 – 30; column 16 line 50 – 54 and column 15 line 17 – 29);*
- *causing the at least one diagnostic medical modality (21) to perform the clinical medical calculation based on the downloaded metric (12); (see at least Kilcommons column 14 line 17 – 47).*

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
13. Claims 1 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killcommons et al. (US 6,424,996 B1) and in further view of "Digital Imaging and Communication in Medicine (DICOM) Standard Part 2.

CLAIM 1

Killcommons as shown discloses the following limitations:

- *retrieving (202) via the World Wide Web (18) a metric (12) associated with the diagnostic medical modality (21); (see at least Kilcommons column 7 line 23 – 43; column 7 line 52 – 55; column 7 line 44 – 46; column 13 line 7 – 16 and column 16 line 29 – 54);*
- *downloading (206) to the diagnostic medical modality (21); (see at least Kilcommons column 13 line 7 – 16).*

Examiner notes that Killcommons discloses that the server contains a protocol database and may gather protocols from any number of sources.

Killcommons does not specifically disclose that the metric is verified, however, the DICOM Standard defines the communication protocol for data files containing digital images in medicine and that it verifies the file set.

- *verifying (204) the integrity (20) of the metric (12); (see at least DICOM Standard Part 2 page 15);*

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the medical information transfer system of Killcommons with the DICOM Standard because using the DICOM standard allows for a common communications protocol between medical modalities and other computers.

CLAIM 2

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *computer-readable storage medium having stored thereon one or more software programs (24) which, when executed, implement the method of claim 1; (see at least Kilcommons column 4 line 54 – 58).*

CLAIM 3

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *based on a request from the diagnostic medical modality, retrieving the metric from the World Wide Web; (see at least Kilcommons column 4 line 3 – 5; column 7 line 52 – 55; column 13 line 7 – 16 and column 16 line 29 – 54).*

CLAIM 4

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *the metric is maintained at a central location; (see at least Kilcommons column 16 line 29 – 54).*

CLAIM 5

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *the central location is one of:*
 - *a web server (3) responsive to a plurality of diagnostic medical modalities at multiple geographic locations; (see at least Kilcommons column 7 line 1 – 14);*
 - *a web server (32) responsive to at least one diagnostic medical modality at a single geographic location; (see at least Kilcommons column 7 line 1 – 14).*

CLAIM 6

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *automatically updating the metric prior to downloading the metric to the diagnostic medical modality; (see at least Kilcommons column 4 line 27 – 30 and column 16 line 50 – 54).*

CLAIM 7

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *automatically downloading an updated metric prior to conducting the medical investigation; (see at least Kilcommons column 4 line 27 – 30; column 16 line 50 – 54 and column 15 line 17 – 29).*

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CLAIM 8

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *maintenance of the metric is separate from maintenance of the software program; (see at least Kilcommons column 1).*

CLAIM 9

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *the metric comprises*
 - *predetermined criteria for performing a medical calculation; (see at least Kilcommons column 6 line 53 – 58 and column 16 line 29 - 54);*
 - *the medical calculation comprising an output of the diagnostic medical modality; (see at least Kilcommons column 14 line 17 – 32).*

14. Claims 10 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killcommons et al. (US 6,424,996 B1) and in further view of "Digital Imaging and Communication in Medicine (DICOM) Standard Part 2.

CLAIM 10

- *requesting (302) the metric (12) from the web server (32, 3); (see at least Kilcommons column 4 line 3 – 5; column 7 line 52 – 55; column 13 line 7 – 16 and column 16 line 29 - 54);*
- *based on the request:*
 - *retrieving (304) the metric (12) from the web server (32, 3); (see at least Kilcommons column 4 line 3 – 5; column 7 line 52 – 55; column 13 line 7 – 16 and column 16 line 29 - 54);*
 - *causing the execution (306) of the software program (38) based on the recognized metric (12); (see at least Kilcommons column 4 line 54 – 67);*

Killcommons does not specifically disclose that the metric is recognized, however, the DICOM Standard defines the communication protocol for data files containing digital images in medicine and that it verifies the file set, i.e. recognizes that it is valid and error free.

- *recognizing the metric (12) on the diagnostic medical modality (21);* (see at least DICOM Standard Part 2 page 15).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the medical information transfer system of Killcommons with the DICOM Standard because using the DICOM standard allows for a common communications protocol between medical modalities and other computers.

CLAIM 11

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *computer-readable storage medium (34) having stored thereon one or more software programs which, when executed, implement the method of claim 10;* (see at least Kilcommons column 4 line 54 – 58).

CLAIM 12

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *during the execution of the software program, substantially no interaction occurs between the diagnostic medical modality and the web server (3);* (see at least Kilcommons column 16 line 29 – 54).

CLAIM 13

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *providing to the web server an identifier associated with the diagnostic medical modality;* (see at least Kilcommons column 10 line 38 – 40 and column 11 line 18 – 28).

CLAIM 14

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *the metric comprises:*
 - *predetermined criteria for performing a medical calculation;* (see at least Kilcommons column 6 line 53 – 58 and column 16 line 29 - 54);
 - *the medical calculation comprising an output of the diagnostic medical modality;* (see at least Kilcommons column 14 line 17 – 32).

CLAIM 15

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons also discloses the following limitations:

- *when the software program is executed:*
 - *the diagnostic medical modality is caused to make a clinical measurement;* (see at least Kilcommons column 14 line 17 – 32)
 - *based on the clinical measurement and the metric the medical calculation is performed;* (see at least Kilcommons column 14 line 33 – 47);
 - *the diagnostic medical modality is caused to output the medical calculation;* (see at least Kilcommons column 14 line 58 to column 15 line 16).

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Killcommons et al. (US 6,424,996 B1) and in further view of "Digital Imaging and Communication in Medicine (DICOM) Standard Part 2 and in further view of Barnhill et al. (US 5,769,074 A).

CLAIM 16

The combination of Killcommons/DICOM as shown discloses the limitations shown above. Killcommons/DICOM does not disclose the following limitations, However Barnhill does:

- *when the software program is executed:*

- *the software program estimates a value associated with the medical calculation, the value being dependent on both a clinical measurement made by the diagnostic medical modality and the metric;* (see at least Barnhill column 4 line 15 – 34; column 8 line 63 to column 9 line 11 and column 28 line 25 – 31)

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the medical information transfer system of Killcommons/DICOM with the computer assisted diagnosis of Barnhill because using trained neural networks to calculate a diagnostic value allows a practitioner to determine the severity of the medical condition.

CONCLUSION

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **571-270-5557**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES A. REAGAN** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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/JOHN A. PAULS/

Examiner, Art Unit 4114

Date: 4 February, 2009

/James A. Reagan/
Supervisory Patent Examiner, Art Unit 4114